REMARKS

Prior to the foregoing amendment, claims 1-7, 10-23, 38-45 and 51-62 were pending in the application, with claims 41 and 43 having been withdrawn from consideration as being drawn to a non-elected species as a result of an earlier election requirement and claims 24-37 and 46-50 having been cancelled as a result of an earlier restriction requirement. Pursuant to the May 23, 2005 Office Action, all pending claims stood rejected.

Claim amendments

By the foregoing amendments Applicants have amended claims 2-4, 6-7, 10-12, 14-21, 38, 40, 45, 51-56, 60 and 61; cancelled claims 1, 5, 13, 22-23, 39, 44 and 62; and introduced new claims 63-83. The cancellation of the aforementioned claims was done solely for the purpose of avoiding excess claims fees or because the limitations thereof where brought forward to a parent claim and not as an admission of the lack of or questionable patentability of those claims and no inference of that sort should be taken from their cancellation.

In order to better address the arguments of the Examiner as well as the cited art, Applicants have divided the claims into two subsets. The first subset, which is embraced by independent claims 63 and 38, addresses those embodiments wherein the antimicrobial additive microcapsule contains a plurality of particles of the actual antimicrobial agent. The second subset, which is embraced by new independent claims 64 and 73, addresses those embodiments wherein the microcapsule comprises a single particle of the antimicrobial agent encapsulated in a coating of the hydrophilic polymer. Both concepts are related in that each relies upon the use of a hydrophilic polymer in order to markedly increase the effective size of the underlying particulate antimicrobial agent; thereby increasing the efficacy of those antimicrobial agents when employed in polymer compositions, especially molding composition, fibers, coatings, or the like. Distinguishing the two is the fact that the former employs multiple particles of the antimicrobial agent in a given microcapsule whereas the latter encapsulates a single particle of the antimicrobial agent as well as the fact that the former will tend to have markedly increased particle size. Thus, the first embodiment has the further advantage of creating large reservoirs of the antimicrobial active in a single antimicrobial additive particle for enhanced and long-lived antimicrobial efficacy. Specifically, all of the antimicrobial active present in each microcapsule is potentially accessible; thus, a microcapsule having three particles dispersed in the hydrophilic

polymer will have 3 times the antimicrobial active present in a singe encapsulated antimicrobial active particle. Furthermore, the microcapsules of the first embodiment tend to be much larger, incorporating large numbers of the particles of the antimicrobial agent and are especially effective in molded parts and thick coatings. The microcapsules of the second embodiment, on the other hand, tend to be comparatively smaller, especially since most antimicrobial agents tend to have relatively small particles sizes to begin with. The latter particles are especially beneficial in those applications where the thickness of the polymer or coating is small and the use of larger microcapsules would affect surface appearance. Thus, while the second embodiment, in itself, represents a marked improvement over the state of the art, the first embodiment is not merely a marked improvement but is a generational leap in antimicrobial technology and antimicrobial delivery.

For convenience of examination, the claims pertinent to each embodiment of the present invention are as follows:

First Embodiment

Independent claim 63 and dependent claims 2-4, 6, 7 10-12, 14-21, 51 and 52.

Independent claim 38 and dependent claims 40-43, 45, and 53-56.

Second Embodiment

Independent claim 64 and dependent claims 60 and 65-72.

Independent claim 73 and dependent claims 61 and 74-83.

Further, it is to be noted that the first claim subset of each embodiment pertains to the antimicrobial additive microcapsule and the second to polymer composition in which the microcapsules are incorporated.

Although the majority of the current claim amendments pertain to a modification of the preamble and the claim dependency, several other notable amendments have been made as follows:

- Claim 4 has been amended to incorporate the prior limitation of claim 5, which has now been cancelled.
- Claim 7 has been amended to reflect that the antimicrobial metal ions in the zeolite include silver and, optionally, zinc or copper or both. The amendment is supported by claim 3 as well as the specification at page 10, lines 4 through 18.

- Claim 38 has been further amended to specify the weight percents of each of the two critical components as well as recite the fact that multiple particles of the antimicrobial agent are present in each microcapsule. These amendments are fully supported by the specification as a whole as well as cancelled claims 13 and 23
- Claim 56 has been amended to incorporate a Markush group of the preferred ceramic carriers and is fully supported by claim 6.
- New claims 63-83 all contain limitations and language that are fully supported by the specification as a whole as well as the claims as previously presented. Claim 63 is merely a restated version of original claim 1 but incorporating the same new limitations as noted in claim 38. The claim was rewritten rather than presented in amended fashion for clarity purposes. New independent claims 64 and 73 mimic, for the most part, claims 63 and 38, respectively, except that each specifies that a single particle of the antimicrobial agent is encapsulated. The new dependent claims all mimic the prior dependent claims. Inasmuch as claims 81 and 83 correlate to prior pending claims 41 and 43, which stand withdrawn, it is expected that these claim too will be withdrawn from consideration. They have been presented in the expectation that the current application will be allowed and the withdrawn claims reinstated into the application before grant and issuance.

In light of the foregoing discussion, it is clear that all amendments and new claims are fully supported by the specification as well as the claims as last presented and none of the amendments or claims introduces new matter. Consequently it is respectfully requested that the amendments and new claims be entered.

As a result of the foregoing amendments, the claims pending in the application following entry of the same will be as follows: claims 2-4, 6, 7, 10-12, 14-21,38, 40, 42, 45, 51-56, 60, 61, 63-80 and 82, with claims 41, 43, 81 and 83 deemed withdrawn.

Election/Restrictions

The Examiner has altered the original election of species requirement and, consequently, has reinstated claim 12.

Claim Rejections

Rejection under 35 USC §102(b) or 103(a) over JP 11-222402 ("Osaka")

Claims 1-4, 10, 11, 13-15, 23, 38, 39, 42, and 55 stand rejected under 35 USC §102(b) as being anticipated by or, in the alternative, under 35 USC §103(a) as obvious over Osaka. It is alleged that Osaka expressly discloses "antimicrobial acrylamide particles (mean particle diameter of 60-90 nm, 90-120 nm and 90-120 nm) containing silver (22.8% by wt., 35.2% by wt. and 25.7% by wt.) which are incorporated into Aronix UV-3701 or ARON NS-1200 and hardened to form a film falling with the scope of applicant's claims." In the alternative, it is alleged that "at the very least, the claimed invention is rendered obvious... because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention." Applicants respectfully traverse the rejection and request reconsideration and withdrawal of these rejections.

Osaka discloses organic hydrophilic polymer particles that have functional or reactive sites incorporated into the polymer chains which reactive sites have the ability to bond, through an ionic or coordination bond, to antimicrobial metal ions, including silver. Unlike the compositions of the present invention wherein particles of an ***inorganic*** antimicrobial agent are dispersed in a hydrophilic polymer, Osaka produces an ***organic***, or at best, and organometallic antimicrobial agent that employs an organic polymer as a carrier for antimicrobial metal ions. From a purely functional standpoint, the organic antimicrobial hydrophilic particles of Osaka correspond more closely to the inorganic carrier particles employed in the practice of the present invention rather than the hydrophilic microcapsules in which the former are encapsulated. Specifically, like the preferred ion-exchange antimicrobial agents of the present invention, the hydrophilic polymer particles of Osaka are preferably porous in nature so as to increase their surface area and, thus, enable the carrying of high loads of the antimicrobial metal ion. However, Osaka is an alternative to the inorganic antimicrobial agents employed by Applicants and specifically teaches away from the ceramic particles of Applicants invention. Indeed, a key objective and intent of Osaka is to overcome the art recognized problems associated with inorganic antimicrobial agents, especially silver zeolite antimicrobial agents, including poor dispersability due to the hydrophilic nature of the inorganic carrier, precipitation due to their relatively large size, poor adhesion to the organic binder and the concurrent adverse impact on

mechanical strength of the film formed, and poor transparency and discoloration due to the presence of said inorganic carriers (see Paragraph 003 of the attached translation). Such a teaching away is further supported by Osaka's use of the silver zeolite as a comparative material, demonstrating the improvement in ion release and efficacy by their claimed organic hydrophilic antimicrobial agents as compared to the traditional silver zeolite.

Additionally, although Osaka discloses that particle sizes up to 100μ diameter may be employed, Osaka clearly teaches away from such large particles and towards smaller particles, especially those below 500nm and preferably below or near 100nm diameter. Indeed, one of the key problems with inorganic antimicrobial agents that Osaka tries to address is poor dispersability due to their larger size. To that end, Osaka specifically teaches that the use of smaller, nano-sized particles, will improve the dispersability of their antimicrobial agents in polymer compositions (See Paragraph 0025of the attached translation).

Contrary to the teaching of Osaka, Applicants specifically require an ***inorganic*** antimicrobial agent, and preferably one that comprises an inorganic carrier, most preferably a ceramic carrier, for the antimicrobial metal ions, whose effective particle size is actually and, in practice, significantly increased. In accordance with the teaching of the present invention, these traditional inorganic antimicrobial agents are dispersed in or encapsulated by a hydrophilic polymer at a given weight ratio to form large particles for use as an additive in coatings, polymers and the like. Applicants have found that these encapsulated antimicrobial additives perform better than and/or are more cost effective as compared to the use of the particulate inorganic antimicrobial agents alone. Specifically, as originally shown in relation to the present application and as more technically espoused in the attached Technical Memo entitled "Technical Comparison of AgION Antimicrobial to Nanoparticulate Silver" (AgION TM-9) by Jeffrey A, Trogolo PhD, a co-inventor on the present application, the particle size of an inorganic antimicrobial agent greatly influences the performance of that antimicrobial agent. Specifically, in polymer compositions have the same loading of antimicrobial agent, Dr. Trogolo found that the use of smaller particle sizes, even with higher (in that case 4x) silver contents, results in lower overall silver release and, thus, poorer performance, especially longevity performance. Although the work described in the paper concerns the comparison of non-encapsulated nanoparticles (similar to Osaka) to non-encapsulated microparticles (the same as employed in

making the microencapsulated particles of the present invention), the same phenomenon and results hold true for encapsulated antimicrobial agents. It is the influence of effective particle size that controls. Indeed, referring to the above-mentioned Technical Memo, it is seen that a polymer composition having a 1% loading of the additive particle produced in accordance with Example 2 (100 micron particles containing 1.25% silver) of the present patent application will provide/have available nearly 35 times the amount of silver per square centimeter of polymer surface area (~1250 ng/cm^2) than a similarly loaded polymer employing the highest silver content nanoparticles of Osaka (0.1 micron particles containing 35.2 silver)(~35.2 ng/cm2). Thus, by increasing the effective particle size of an antimicrobial agent through the use of a hydrophilic polymer, one increases the probability that that any given particle will touch or be present at the surface of the polymer composition into which it is incorporated. In following, by increasing the probability that a given particle will touch or be present at the surface, one increases the number of particles that actually do touch or are in intimate proximity to the surface, thereby increasing the amount of antimicrobial active able to provide antimicrobial efficacy without increasing the amount of antimicrobial agent added to the polymer composition.

The impact of the present invention is even more significant in those compositions wherein the antimicrobial additive comprises multiple particles of the inorganic antimicrobial agent in a single hydrophilic polymer particle. Here, if any part of the antimicrobial additive particle touches the surface of the non-hydrophilic polymer, all of the antimicrobial active in that particle, i.e., the combined amount of antimicrobial active carried by all of the encapsulated inorganic particles, will be accessible and provide antimicrobial efficacy. Thus, the antimicrobial additive particles of the present invention serve as reservoirs of the antimicrobial active, providing long-term efficacy, without increasing the amount of active or silver within the antimicrobial agent particles themselves.

In light of the foregoing discussion, it is clear that both aspects of the present invention provide more antimicrobial efficacy for a given amount of antimicrobial agent than would have been achieved or achievable for the non-encapsulated materials and, furthermore, do so more cost effectively. In this respect, one could actually lower the amount of antimicrobial agent employed and still provide the same or better performance at a lower cost. In this respect, it is well recognized in the art that antimicrobial agents below the surface of non-hydrophilic

polymers cannot release their actives and do not participate in providing antimicrobial efficacy unless the polymer is worn away to expose the particle. While the latter happenstance may occur in some limited applications, this is not the rule for most typical applications and, thus, the antimicrobial agent below the surface is essentially wasted. In contrast, the use of the microencapsulated particles of the present invention makes more of the antimicrobial active available at the surface, thus providing for less waste and more bioefficacy.

It is also important to note that the organic hydrophilic antimicrobial agents of Osaka release by dissociation: thus, if water is present, the antimicrobial metal ion will release. While this same release will be seen with some of the antimicrobial agents suitable for use in the practice of the present invention, namely the inorganic salts and the dissolving glass materials, such will not be seen with Applicants' preferred antimicrobial agents, namely the ion-exchange type agents. These will only release the antimicrobial metal ion in an effective amount if another cation is present to complete the exchange. Thus, when used in high humidity environments or applications where multiple washings will occur, their longevity is preserved as compared to those antimicrobial agents that merely rely upon dissociation.

Further distinguishing the present invention from Osaka, both from an anticipatory as well as obviousness perspective, is the amount of silver release. Osaka employs high loadings of silver ion, almost 10 times that of the typical silver zeolite (See Osaka examples). Presumably this high loading is to help overcome the problem that Applicants have identified, which Osaka had not, with respect to antimicrobial particles below the surface. Specifically, the much higher loading of the organic particles of Osaka will help compensate for the lower percentage of particles that actually touch the surface. However, this presents a new and commercially significant problem not addressed nor appreciated by Osaka. Specifically, the regulatory agencies, like the US EPA, require all pesticides to be registered and their uses approved. Such registrations limit the amount of the antimicrobial active, in this case the antimicrobial metal or metal ion, that may be incorporated into any material or article of manufacture. Thus, while an agency may allow the use of the higher concentration employed by Osaka, in order to maintain the overall limit on the level of antimicrobial active allowed, one would have to reduce the amount of the Osaka materials one could use. Applicants, on the other hand, get a marked

increase in antimicrobial efficacy and release without changing the amount of antimicrobial incorporated at the outset.

In light of the foregoing discussion, it is clear that Osaka does not anticipate nor make obvious the compositions of the present invention. As noted, contrary to the allegation made that both make use of the same materials, Osaka and the present Applicants employ two different and distinct antimicrobial additives. Osaka employs a hydrophilic organic polymer in particulate form which organic polymer has incorporated into the polymer chain functional groups that bond to antimicrobial metal ions. Applicants, on the other hand, employ microcapsules of a hydrophilic polymer that contains one or more inorganic antimicrobial agents in particulate form where, if the active is a metal ion, the metal ion is bonded to an inorganic carrier, not the polymer encapsulating material. Furthermore, Applicants increase the particle size of their antimicrobial agents whereas Osaka desires to minimize their particle size. Indeed, comparing the 100μ diameter particles of Applicants examples with the ~100nm diameter particles of Osaka, the former are 1000x larger in diameter and 10^9 times larger overall. Thus, the rejection for anticipation or, in the alternative, obviousness over Osaka is without merit and should be withdrawn.

Rejection under 35 USC §103(a) over Osaka in view of JP 4-66512 ("Shintokogio") and Turner et. al. (US 2003/0043341)

Claims 1-4, 10-17, 19-21, 23, 38-40, 42, 44, 45, 51-55 and 58 stand rejected under 35 USC §103(a) as being unpatentable over Osaka in view of Shintokogio and Turner et. al. Osaka is cited for the teachings set forth above as well as for teaching that the hydrophilic polymers are compatible with hydrophobic polymers, that the antibacterial metal can be in the form of a complex with a quarternary ammonium compound which also has antibacterial activity and that the resin may be selected from polyethylene, polypropylene, ABS, epoxy resin, styrene resin, and polyvinylchloride. Shintokogio is cited as teaching an antimicrobial silver salt coated with polyurethane resin prepared from polyisocyanate and incorporating the same in thermoplastic and thermoset resins. Turner et. al. is cited as disclosing sodium nitrate reducing discoloration caused by silver.

Other than noting what each reference is cited for, the Examiner makes no arguments against the patentability of the present claims and fails to discuss how these references are to be

combined for that purpose. Consequently, Applicants cannot respond and is it hereby requested that this particular rejection be withdrawn. Nevertheless, it is likely that the following discussion concerning the subsequent grounds of rejection, alone or in combination with the foregoing, will embrace and address what may have been the intended basis for the Examiner's rejection.

Rejection under 35 USC §103(a) over Shintokogio in view of Takebayashi et. al. (US 6,113,936), Niira et. al. (US 5,556,699), Wada et. al. (US 3,981,970) and Turner et. al.

Claims 1-7, 10-23, 38-40, 42, 44, 45 and 51-62 stand rejected under 35 USC §103(a) as being unpatentable over Shintokogio in view of Takebayashi et. al., Niira et al., Wada et. al., and Turner et. al. for the reasons of record and the following:

- Shintokogio is cited as teaching coating silver zeolite with polyurethane and incorporating the same in thermoplastic and thermoset resins for providing antimicrobial activity. The silver zeolites are prepared by addition of silver nitrate and ammonia and the so formed materials are coated with from 1.5% to 3% by weight of the polyurethane resin.

- Takebayashi et. al. teach a method of microencapsulating silver zeolite with polyurethane where the average diameter of the obtained microcapsule is usually from 0.1 to 300μ, preferably from 0.5 to 200μ and the core particle is usually from 0.1 to 200μ, preferably from 0.5 to 100μ.

- Niira et. al. is cited as teaching antibiotic silver zeolites further incorporating ammonium ions for the prevention of discoloration of resins into which they are incorporated.

- Wada et al. is cited as teaching the equilibrium reaction for cation-exchange in zeolites, including the exchange process where silver ions are introduced to sodium containing zeolite whereby silver zeolites and excess silver ions and sodium ions result, as well as an exchange process where nitric acid is introduced to silver zeolite with the result being hydrogen zeolite, silver nitrate and excess nitric acid.

- Turner et. al. is cited as teaching that sodium nitrate reduces discoloration caused by silver.

In making its rejection, the Patent Office acknowledges that the prior art does not expressly disclose an inorganic antimicrobial which is encapsulated with hydrophilic polymer having an average diameter or 2000 microns or less, optionally further comprising an ammonium

salt or sodium nitrate or optionally further incorporated into an addition polymer. However, the Patent Office alleges that the prior art amply suggests the same are antibacterial silver zeolites which are incorporated into addition polymers; the combination of antibacterial silver zeolites and hydrophilic polymers, such as polyurethane; and the use of ammonium ions and the exchange of silver with sodium ions and nitric acid. The Patent Office further alleges that it would be well within the skill of one skilled in the art to modify the prior art as Applicants have with the expectation that the combination of antibacterial silver zeolites and hydrophilic polymer would result in increased antimicrobial activity, that the addition of ammonium ions would inhibit discoloration of polymer resin in which the silver zeolite is incorporated and that the addition of a salt of sodium ion and nitric acid, i.e., sodium nitrate, would drive the silver ions out of the zeolite, thereby increasing the amount of free silver ions available for antibacterial effect. The Patent Office states that Applicants' prior arguments have been considered but are rendered moot in light of the new grounds of rejection. In summation the Patent Office states that the present claims are prima facie obvious as every element of the invention has been collectively taught by the combined teachings of the references.

Applicants respectfully traverse the rejection and request reconsideration in light of their prior arguments, which are hereby reiterated and incorporated by reference, and the arguments below. However, before discussing the rejections, and without making any admission as to the above characterization and arguments of the Patent Office, Applicants wish to point out that *prima facie* obviousness is not founded on the mere presence of each element of the claimed invention in a plurality of references. Rather, the Patent Office must look at the whole of the teachings of the prior art as well as the distinctions between the prior art and the presently claimed invention. As part of this assessment, especially in addressing what is alleged to be merely a combination of old elements, the Patent Office must also provide proofs that the cited references teach, suggest or motivate the combination of the specific prior art references in such a way as to arrive at the particular combination with its attendant properties/performance as claimed by Applicants. The Patent Office has failed in these respects.

Turning now to the rejection itself, like Osaka, mentioned above, Shintokogio (formerly addressed as Hashida in the prior response) endeavors to address two key problems associated with the use of inorganic antimicrobial agents in hydrophobic resins: poor dispersability due to

the hydrophilic nature of the surface of the inorganic antimicrobial particles and discoloration due to the interaction of the antimicrobial metal ions with residual constituents of the resins into which they are incorporated. However, unlike Osaka who creates a new type of antimicrobial material, a hydrophilic polymer having pendant antimicrobial metal ions bonded thereto, Shintokogio coats the hydrophilic particles with from 0.1 to 5% by weight (based on the weight of the antimicrobial agent) of a non-hygroscopic polyurethane resins. Nothing is said nor suggested with respect to intentionally and significantly increasing the effective particle size of the inorganic antimicrobial agent or of employing hydrophilic polyurethane. Though the polyurethane employed by Shintokogio had a very low water content to begin, it is below even the minimum water content required of Applicants' hydrophilic materials and markedly below Applicants' preferred water content. Furthermore, it is clear that Shintokogio is not interested in hydrophilic polymers and, in fact, does not want its polymers to absorb water. Specifically, Shintokogio requires the use of non-hygroscopic polyurethane: a feature that is elucidated upon and demonstrated by the results shown in its Table 1 where no water uptake was found with the polyurethane even after the polyurethane had undergone high temperature (150^0C) processing.

Additionally, though the polyurethane coating of Shintokogio will increase the particle size, the increase is insubstantial at the level of coating allowed. Specifically, looking at the example of Shintokogio wherein a zeolite particle of 3.5 microns diameter is coated with 3% by weight of a polyurethane, the maximum likely thickness of the coating will only be on the order of 0.08 microns, merely 8% that of the minimum thickness according the those embodiments of the present invention where individual particles are coated.[a] Furthermore, encapsulating the

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a. wt% = $[4/3\pi(r_b^3 - r_a^3)D_1]/[4/3\pi(r_b^3 - r_a^3)(D_1) + 4/3\pi r_a^3 (D_2)]$ wherein r_a is the radius of the zeolite particle, r_b is the radius of the polyurethane coated particle, D_1 is the density of the polyurethane and D_2 is the density of the silver zeolite particle. With a coating of 3% by weight and $r_a = 1.75$ microns where $D_2 = D_1$, $r_b = \sim 1.77$ microns for a 0.02 micron thick coating; where $D_2 = 5D_1$, $r_b = \sim 1.83$ microns for a 0.08 micron thick coating, and when $D_2 = 10D_1$, $r_b = \sim 1.91$ microns for a 0.16 micron thick coating. While the densities of the materials in Shintokogio are not known, it is most likely that the density of the silver zeolite will be between 1 and 5 times that of the polyurethane. Thus, the likely maximum thickness of the coating would be about 0.08 microns.

individual particles of Shintokogio with the minimum 1 micron coating required according to the present invention increases the effective particle size nearly 290% whereas the maximum coating thickness according to Shintokogio only increases the effective particle size by 14%.[b] Since the coating of Shintokogio is only employed to provide better compatibility at the polymer/zeolite interface, i.e., to alter the highly hydrophilic nature of the un-encapsulated zeolite; there is no motivation or reason to increase the coating thickness beyond that needed to alter the surface. Thus, Shintokogio fails to provide any suggestion, motivation or teaching to substantially increase the effective particle size of an inorganic antimicrobial agent in order to increase its effectiveness.

Although the Patent Office has cited a different Takebayashi et. al. patent in this Office Action, the teachings and specifications are quite similar to those of the earlier reference and the same arguments as previously presented are applicable here. Takebayashi et al., like Lew et. al. (to be discussed below), seek to coat or encapsulate fungicides, insecticides and other agrichemicals for the purpose of protecting workers, especially those that formulate and dispense the agrichemicals, from exposure to the same; protecting the agrichemical actives themselves from exposure to atmospheric conditions and chemicals that may cause them to degrade and/or affect the efficacy of the actives; and for helping regulate the rate at which the active is available to perform. Though Takebayashi et al. do mention silver zeolite along with but a handful of inorganic materials that may be coated; these few inorganic agents are buried in a long listing of suitable, organic agrichemicals to which the invention is believed applicable, one that extends over nearly eighty lines of the patent specification. Furthermore, Takebayashi employs two distinctly different polymer/polymerizable materials in its encapsulation process. The first and most critical is a non-ionic substance which acts as a surfactant to improve dispersability of the active in the solution for the actual encapsulation step. The second is the encapsulating composition whose only requirement seems to be that it is a condensation polymerizable material. Takebayashi et. al. provide an extensive list of suitable monomers and resultant

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b. $288\% = [4/3\pi(r_m^3-r^3)]/[4/3\pi\, r^3]$, $14\% = [4/3\pi(r_s^3-r^3)]/[4/3\pi\, r^3]$; where $r = 1.75\mu$, $r_s = 1.83\mu$ (the maximum likely radius of the coated particle of the example in Shintokogio) and $r_m = 2.75\mu$ (the minimum possible particle size of the same antimicrobial particle of Shintokogio according to the present invention.

condensation polymer materials, yet no mention is made as to whether they are or even can be hydrophilic. Furthermore, although Takebayashi et. al. do set forth certain particle size ranges, they do not ascribe any criticality or importance to the same and, when even a hint of importance is made relative to particle size, it is made with respect to the particle size of the core particle, i.e., the antimicrobial agent itself, not the encapsulated particle. Clearly, though, Takebayashi et. al. are not concerned with substantially increasing the effective particle size of an antimicrobial agent by the use of hydrophilic polymers to markedly increase their effectiveness in polymer compositions and the like as compared to such compositions incorporating the un-encapsulated antimicrobial agents at similar loadings. Furthermore, Takebayashi et. al. do not contemplate the incorporation of multiple particles of the antimicrobial agent in a given microcapsule and such would be contrary to their teaching since the whole purpose of the nonionic material, the key critical component of Takebayashi et. al., is to enhance the dispersion of the antimicrobial particles.

In light of the foregoing discussion, it is clear that neither Shintokogio nor Takebayashi et. al. alone or in combination teach, motivate or suggest the preparation of individually encapsulated antimicrobial agents wherein the encapsulating material is a hydrophilic polymer whose water content is at least 5 weight percent and is present at a coating thickness of between 1 micron and 15 microns let alone the desirability and benefits of doing so for increasing the effective particle size and enhancing the effectiveness of the antimicrobial agent when incorporated into a polymer material, either as a molding composition, coating or the like. Furthermore, neither reference teaches, suggests or motivates one to encapsulate a plurality of particles of an antimicrobial agent into a single microcapsule for the purpose of increasing the effective particle size as well as markedly enhancing the antimicrobial efficacy thereof by creating large reservoirs of antimicrobial active. Consequently, the Patent Office has not proven or established prima facie obviousness of the present invention as the prior art does not disclose or suggest the specific and key limitations and requirements of the present compositions or the unexpected and marked benefits attained thereby nor do they motivate one to make the specific modifications required by Applicants' compositions.

As noted above, Niira et. al. is cited as teaching ammonium ions in antimicrobial agents for reduced discoloration. Though it is not explicitly stated, it is believe that this rejection is

directed towards dependent claims 17 and 18. While the Patent Office is correct in that Niira et. al. teach ammonium ions as being effective for reducing discoloration or resins upon incorporating silver zeolites, such prevention is not complete. Discoloration is reduced not eliminated. In accordance with the present invention, it is found that the combination of the ammonium compounds with the encapsulation provide even more improved inhibition of discoloration. This is due to the finding that discoloration is predominately, if not completely, restricted to the microcapsule and is not seen, at least not to any significant extent, in the matrix resin into which the microcapsules are incorporated. Consequently, although the polymer microcapsule will discolor, such discoloration will not be apparent when viewing the polymer into which it is incorporated. Thus, this unexpected benefit of the combination of the presence of the ammonium ions with the microencapsulation is patentable over Niira et. al., alone or in combination with Shintokogio and Takebayashi et. al., since none of the citations or their combined teachings teach or suggest that microencapsulation and ammonium will further reduce the known discoloration effect of silver zeolites in polymers. Thus, the rejection should be withdrawn.

The citation of Wada et. al. and Turner et. al. for disclosing the use of a doping agent such as sodium nitrate to initiate a burst of ion release from the antimicrobial additives of the present invention is not supported nor warranted as argued in Applicants' prior response which is hereby reiterated and incorporated by reference. In particular, Applicants again reiterate that the specific teaching of Wada et. al. is the creation of unique zeolite materials suitable for use in the recovery of metals/metal ions from waster water. The need for these unique zeolites is due to the fact that the most efficient recovery method employs nitric acid which dissolves typical zeolites, like zeolite type A, the very zeolite used in the present invention. Furthermore, nothing in Wada et. al. suggests or teaches the use of sodium nitrate as a dopant for enhancing the release of silver ions from a zeolite carrier. Specifically, in the first step of the two-step reaction mechanism of Wada et. al. shown at Column 3, lines 5-11, sodium ions in the specialty zeolite are fully exchanged with silver ions to render a silver zeolite. In the second step, the isolated/recovered silver zeolite is then washed at elevated temperatures with nitric acid to remove the silver ions by an exchange with the hydrogen atom of the nitric acid. Neither sodium nitrate nor any dopant is found or suggested. Similarly, in the first step of the second two-step

reaction mechanism shown at Column 3, lines 22-30, potassium ions in the specialty zeolite are fully exchanged with a combination of sodium and silver ions to render a sodium/silver zeolite. In the second step, the isolated/recovered sodium/silver zeolite is then washed at elevated temperatures with nitric acid to remove the sodium and silver ions by an exchange with the hydrogen atom of the nitric acid. Here, both silver nitrate and sodium nitrate are formed: there is no release of free silver ions. Nothing here would suggest that a dopant, or sodium nitrate in particular, would have the capability of increasing or expediting the release of silver ions from a traditional zeolite let alone the unique zeolites of Wada et. al.

Finally, as noted by the Patent Office, Turner et. al. suggest the use of sodium nitrate as an additive to reduce discoloration of polymers due to the presence of silver. Here the sodium nitrate acts as an oxidizing agent for oxidation of silver. Though it is not clear whether the use of the oxidizing agent is applicable to those embodiments of Turner et. al. that employ silver zeolites, if it is then presumably the Ag^+ ions of the zeolite are oxidized to the Ag^{++} state which renders it less likely to cause discoloration. What affect, if any, it may have on the bioactivity of the silver is not discussed. Regardless, the use of sodium nitrate and other dopants as a means to increase or expedite the release of silver ions, as taught by the present invention, would seem to be contraindicated by Turner et. al. One aspect of Turner et. al. that seems to have eluded the Patent Office is its teaching and desirability for coating the zeolites with a hydrophobic polymer for slowing down the release of silver ions. Turner then would certainly not seek to incorporate a dopant whose express purpose is to increase the release of silver ions while concurrently encapsulating the zeolite with an hydrophobic polymer to slow the release of silver ions. Furthermore, nothing in Turner et. al., alone or in combination with the aforementioned references teach or suggest or motivate one to prepare antimicrobial additives as claimed by the present invention or polymer compositions containing the same which have improved efficacy and cost effectiveness. Finally, nothing in either Wada et. al. or Turner et. al. even hint at the reduction in discoloration in polymer compositions incorporating zeolites as a result of coating the latter in hydrophilic polymers, thereby significantly, if not completely, limiting the formation of discoloration to the polymer coating and not to the matrix polymer itself.

For all the reasons set forth above, it is clear that the Patent Office has not proven or demonstrated prima facie obviousness. None of the references alone or together teach or even

suggest Applicants specific antimicrobial additives or antimicrobial compositions containing such additives, none of them teach or suggest the ability to increase the antimicrobial efficacy of a composition by increasing its effective particle size, none of them teach or suggest the benefits of enhanced antimicrobial activity as a result of creating reservoirs of antimicrobial active in hydrophilic polymer particles, and none teach or suggest the other benefits of the additives of the present invention and their use as discussed above and in the specification. Consequently, the rejection based on Shintokogio in view of Takebayashi et. al., Niira et. al., Wada et. al. and Turner et. al. fails and should be withdrawn and all claims passed on to allowance.

Rejection under 35 USC §103(a) over Lew et. al. (US 5,599,583)

Claims 1-4, 10, 11, 13-15, 22, 23, 51, 52 and 59-62 stand rejected under 35 USC §103(a) as being unpatentable over Lew et. al. It is alleged that Lew et. al. disclose encapsulation of fungicides such as copper salts with water soluble polymers including PEG strengthened with polyvinylpyrrolidone wherein the active ingredient solids have a particle size of less than about 100 microns and the encapsulated materials a particle size of from 150 microns to 1500 microns. It is stated that the difference between the prior art and the claimed invention is that the former does not expressly disclose an inorganic antimicrobial encapsulated in a hydrophilic polymer having an average particles size of less than about 2000 microns. The Patent Office concludes that the presently claimed invention would have been prima facie obvious as it would have been well within the skill of one of ordinary skill in the art and one would have been motivated to modify the prior art as above with the expectation that the encapsulation would render the copper salts easy to handle, reduce or eliminate exposure concerns and provide a measure of control over the rate, timing and duration of the copper salt. Applicants respectfully traverse the rejection and request reconsideration.

First, Applicants question the basis for and form of the rejection itself. Rather than argue that the art leads one to the present invention, the Patent Office does the opposite, taking a hindsight approach and asserting that having seen what Applicants have done, it would be obvious to create the art from Applicants' invention. This is not the proper form or basis for establishing prima facie obviousness. In establishing prima facie obviousness, among the showings to be made by the Patent Office are that there is some motivation, suggestion or teaching in the prior art to make the claimed modifications, that the art teaches the expected

result and that those results will be produced successfully. By taking the approach it has, the Patent Office has ignored the specific teachings and limitation of the claimed invention and discredited the specific attributes and benefits attained by the claimed invention.

Regardless, Lew et. al. do not render obvious the present invention. Lew et. al., like Takebayashi et. al., are concerned with rendering agrichemicals more user friendly and safe for handling as well as with controlling the rate of release of the agrichemicals themselves. Lew et. al. achieve this by incorporating the agrichemical into a soluble polymer whereby, through the selection or creation of polymers of certain solubility parameters, they can control the rate at which the polymer dissolves and, thereby, releases the entrained agrichemical. Essentially, Lew et. al. employ materials that perform similar to a Tootsie-Roll Pop where once the candy coating is dissolved, the encased Tootsie Roll is exposed, except here once the coating dissolves the agrichemical active is released. This contrasts with the microcapsules of the present invention wherein the antimicrobial active is encased in or incorporated into particles of a hydrophilic polymer that, unlike the required soluble polymers of Lew et. al., do not dissolve. Instead, they absorb water which water causes the polymer to swell thereby creating aqueous pathways through the polymer for the antimicrobial active. Further, in the case of the ion exchange type materials, release of the antimicrobial active also requires the absorption of cations into the hydrophilic polymer to exchange with the antimicrobial metal ions. Thus while the soluble polymers of Lew et. al. would continually release as water dissolved the soluble polymer, no antimicrobial active would be released in the case of the ion-exchange type agents unless and until exchange ions are present, regardless of the amount of water passing over the additive particles. Furthermore, Lew et. al. regulate the release rate of their agrichemicals by altering the thickness of the coatings or choosing slower dissolving polymers. Thus, one may handle the materials of Lew et. al. without concern for personal contact since they are designed not to release the active until all or a sufficient amount of the encapsulating material is dissolved. However, such is not necessarily the case with Applicants compositions. Specifically, antimicrobial release is likely just holding Applicants materials in a moist hand where both moisture and exchange ions such as sodium are readily present.

Given the marked difference and distinction between the soluble polymers of Lew et. al. and the hydrophilic polymers of Applicants, it is clear that those skilled in the art would not be

motivated to encapsulate the agrichemicals of Lew et. al. with the hydrophilic polymers of Applicants. Furthermore, as noted above, contrary to the assertion of the Patent Office, if one did, one would not achieve the same results as would be expected with a soluble polymer. Thus, the Patent Office has failed to establish a prima facie obviousness and the rejection should be withdrawn and the claims passed on to allowance.

Rejection under 35 USC §103(a) over Stapler et. al. (US 5,382,424)

Claims 1-4, 10, 11, 13-17, 22 and 59-62 stand rejected under 35 USC §103(a) as being unpatentable over Stapler et. al. It is alleged that Stapler et. al. teach the encapsulation of various antimicrobials, including quaternary ammonium salts and zinc and copper salts, in gelatin, polyvinyl alcohol sucrose esters, and other similar materials wherein the shell thickness is on the order of 30 microns to 2 mm, preferably 70 to 110 microns, the overall particle diameter of the encapsulated antimicrobial is from about 2mm to about 9mm, preferably from about 3mm to about 7mm and the antimicrobial comprises from about 0.001% to about 2% of the total core contents. It is stated that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose an inorganic antimicrobial which is encapsulated with a hydrophilic polymer having an average diameter of about 2000 microns. However, the Patent Office contends that the prior art amply suggests the same and that those skilled in that art would be motivated to modify the prior as above with the expectation that the encapsulation of a core containing the antimicrobial would allow control of breath odor without having to expectorate as with a mouthwash and that the combination of the ammonium compound and copper and/or zinc salt with the expectation that the combination would also have antimicrobial activity. Applicants respectfully traverse the rejection and request reconsideration.

First, as with the preceding rejection, Applicants question the basis for and form of the rejection itself. Rather than argue that the art leads one to the present invention, the Patent Office has once again taken the hindsight approach that if one could modify the prior art in the manner taught by the Applicants and that modification produces the results desired by the prior art, then it is obvious. Such an approach completely ignores and discredits the specific limitation and requirements of the claims of the present invention as well as the benefits and attributes of the present invention. This is not the proper form or basis for establishing prima

facie obviousness, especially where the materials and objectives of each are different and the results of one are not shown or inherent in the other or even attainable by the other.

Secondly, Stapler et. al. is non-analogous art. One would not look to art for preparing breath protection microcapsules for creating improved antimicrobial agents for incorporation into polymer materials.

Regardless, in spite of their very limited teachings and lack of disclosure, it is clear that Stapler et. al. do not render obvious the present invention. Stapler et. al. is directed towards tablets for insertion into the mouth for improving breath odor. This is achieved by dissolving the breath control active/antimicrobial in an organic diluent, typically along with a number of other additives, which is then encapsulated in a number of different materials that are suitable for ingestion and retention in the mouth. Because of their use, the size of the microcapsules are quite large, and the shell thickness quite thick in comparison to the encapsulated antimicrobial agents of the present invention. Furthermore, Staple et. al. speak of addressing prior problems associated with efforts to encapsulate breath protection actives/antimicrobials including solubility issues and premature release through the use of select diluents and the subsequent encapsulation of the liquid droplets. Applicants, on the other hand, specifically teach particulate inorganic antimicrobial agents, not liquid solutions containing an antimicrobial agent. Also, Stapler et. al. require that the breath control active/antimicrobial dissolve in the diluent; however, it is clear that many of Applicants antimicrobial agents, especially its preferred antimicrobial agents, will not dissolve. Finally, though it is not clear, it appears that the capsule shell materials, like those of Lew et. al., are soluble materials in contrast to the strongly hydrophilic materials required by the present invention. Indeed, given the objective of Stapler et. al. and the material included in the liquid core of the microcapsules, it would seem that the hydrophilic materials of applicants would be inappropriate.

Inasmuch as Stapler et. al. is non-analogous and, in any event, teaches away from the direction of the presently claimed invention as well as employs different, though at times overlapping, materials, different particle sizes, etc.; Applicants do not believe that the Patent Office has established prima facie obviousness. Consequently, the rejection over Stapler et. al. should be withdrawn and the claims passed on to allowance.

Double Patenting

Claims 1-7, 10-23, 38-40, 42,44, 45, and 51-62 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-7, 10-22, 33, 34, 45 and 47-62 of copending Application No. 10/032,370 in view of Hagiwara et. al. (US 4,775,585) and Konagaya et. al. (US 6,013,275).

Though Applicants believe the claims of their co-pending application are distinct from and patentable over the presently claimed invention due to its claimed high aspect ratio and the different performance attained thereby, in the interest of expediting allowance and issuance of a the present application, Applicants herewith submit a terminal disclaimer together with the appropriate fee of $135.00.

Conclusion

Contrary to the assertions of the Patent Office, none of the foregoing grounds of rejection or any of the cited art, alone or in combination, speaks of, suggests, infers or motivates one to produce the particulate, encapsulated antimicrobial agents of the present invention and employ them in polymer compositions as a discrete second phase for enhanced antimicrobial efficacy and control. Similarly, none of the cited art, alone or in combination, would suggest the marked benefits attained by compositions made in accordance with the teaching of the present invention as described in the specification and as shown by way of additional examples in Applicants corresponding Published International PCT Patent Application No. WO03/055941.

Though the Patent Office has searched through a number of patent publications to find elements that, at first glance, appeared to disclose elements according the instant invention, it has not provided any basis or pointed to any text or passages of the references which would explain why those elements are to be combined or even that they could be combined. Nothing in the art supports or suggests i) the encapsulation of individual particles of an inorganic antimicrobial agent with a hydrophilic polymer, ii) the preparation of micro-sized particles comprising a hydrophilic polymer having dispersed therein a plurality of particles of an inorganic antimicrobial agent, iii) the use of (i) or (ii) as an antimicrobial additive in a polymer composition, iv) that the compositions of (iii) have markedly and unexpectedly better performance and cost efficiency as compared to similar polymer compositions wherein the antimicrobial agent is not encapsulated with a hydrophilic polymer, etc. Clearly, the Patent

Office has failed to present a valid argument of prima facie obviousness and, in any event, Applicants have fully rebutted any such claim. Consequently, Applicants believe the claims as currently presented represent patentable subject matter and respectfully request that the rejections be withdrawn and the application passed on to allowance.

Petition For Extension of Time

By this response, Applicants hereby petition for a three-month extension of time; thereby extending the response period from August 23, 2005 to and including November 23, 2005. Enclosed is payment of the Petition Fee in the amount of $510.00.

Claims Fees

Following the amendment, the number of independent claims is 4, two less than the highest number of independent claims previously paid for, and the total number of claims is 51, one more than the highest number previously paid for. Thus, Applicants also enclose payment in the amount of $25.00 for one additional claim.

Credit Card Authorization

Accompanying this Amendment and Response is a Credit Card Authorization in the amount of $665.00 to cover the aforementioned Terminal Disclaimer Fee (1.20(d)), Extra Claim Fee (1.16(i)) and Extension of Time Fee (1.17(a)(3)).

Applicants believe all matters raised in the Office Action have been fully addressed. Should there be any questions, please contact the undersigned, Applicant's attorney.

Respectfully submitted,

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